



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-21-21GH; Docket No. CDC-2021-0065]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum. This proposed collection will collect data to evaluate the efficacy of using administrative insurance and prescription claims (billing) data to identify and intervene upon persons with HIV who fail to fill antiretroviral (ARV) prescriptions.

**DATES:** CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No.

CDC-2021-0065 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also

requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

## Proposed Project

Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum - New - National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Use of HIV surveillance data to identify out-of-care persons is one strategy for identifying and re-engaging out-of-care persons, and is called Data-to-Care or "D2C." Data-to-Care uses laboratory reports (i.e., CD4 and HIV viral load test results) received by a health department's HIV surveillance program as markers of HIV care. In the current D2C model, there is a delay in the identification of out-of-care persons due to the time interval between recommended monitoring tests (i.e., every three to six months) and the subsequent reporting of these tests to surveillance.

Insurance and prescription administrative claims (billing) data can be used to identify persons who fail to fill antiretroviral (ARV) prescriptions and who are at risk for falling out of care. Because most ARVs are prescribed as a 30-day supply of medication, prescription claims can be used to identify persons who are not filling ARV prescriptions on a monthly basis. Tracking ARV refill data can, therefore, be a more real-time indicator of poor adherence and can act as a harbinger of potential poor retention in care. Using real time

insurance and prescription claims data to identify persons who fail to fill ARV prescriptions, and to intervene, could have a significant impact on ARV therapy adherence, viral suppression and potentially on retention in care.

The purpose of the Antiretroviral Improvement among Medicaid Enrollees (AIMS) study is to develop, implement and evaluate a D2C strategy that uses Medicaid insurance and prescription claims data to identify; 1) persons with HIV who have never been prescribed ARV therapy, and 2) persons with HIV who fail to pick up prescribed ARV medications in a timely manner, and to target these individuals for adherence interventions.

A validated HIV case identification algorithm will be applied to the Virginia Medicaid database to identify persons with HIV who have either never filled an ARV prescription or have not filled an ARV prescription within >30 to <90 days of the expected fill date. Deterministic and probabilistic methods will be used to link this list to the Virginia Department of Health's (VDH) Care Markers database (an extract of the VDH HIV surveillance database). Individuals that are matched across the two databases (indicating that the persons are both enrolled in Medicaid and confirmed HIV positive) are eligible for study participation. Additional eligibility criteria include age 19 - 63 years and continuous enrollment in Virginia Medicaid for the preceding 12 months.

Cluster randomization will occur at the healthcare provider level and will be conducted concurrently with the initial potential participant screening. Providers will be randomized to either the intervention arm or to the usual care arm (i.e., no intervention or control arm). Study participants are the patients of the randomized healthcare providers. Participants in the intervention arm will be delegated to either a patient-level or provider-level intervention, depending on need; participants who are >30 to <90 days late filling their ARV prescription(s) will receive the patient-level intervention, and participants who have never filled an ARV prescription will be delegated to the provider-level intervention. Participants of the provider-level intervention will not receive direct intervention. Instead, the healthcare providers of these patients ("provider participants") will receive the provider-level intervention. Potential participants will be contacted by a study Linkage Coordinator to explain the study and obtain consent for participation.

The patient-level intervention has two phases. Phase I is intended for patients who are >30 to <60 days late filling their ARV prescription(s). In Phase I, a Linkage Coordinator will contact participants to discuss the participants' adherence barriers. Once the participant's adherence barriers are identified, the participant will be referred to appropriate resources to assist them in overcoming their adherence barrier(s). Phase II is intended for patients who were enrolled

in Phase I but who failed to fill their ARV prescriptions in the subsequent 30 days of the Phase I consultation, and for participants who are >60 to <90 days late at the time the participant was determined to be study eligible. In Phase II, the Linkage Coordinator will lead a similar consultation as in Phase I, but will probe for more complex adherence barriers (e.g., mental health concerns) and referrals will be made accordingly. The participant will also be offered an evidence-informed mobile application ("app") which is designed to support ART adherence and retention in care.

The provider-level intervention will consist of a peer-to-peer clinician consultation delivered by clinicians from the Virginia Department of Health's Advisory Committee to the Virginia Medication Assistance Program or by another HIV clinical expert. The peer-to-peer clinician consultations will involve introduction or reinforcement of HIV clinical guidelines for ART initiation, strategies to optimize ART adherence, and resources for supporting adherence for people with HIV. The consultation will be tailored to the needs of the provider participant.

All analyses will be conducted at the patient level. Persons within the intervention arm will be followed prospectively for 12 months. At the end of the intervention arm follow-up period, persons within the usual care arm will be followed retrospectively for 12 months. The primary study

outcome of HIV viral suppression (HIV RNA < 200 copies/mL) will be compared between study arms.

CDC requests OMB approval to collect standardized information from 500 AIMS study participants (460 participants of the patient-level intervention and 40 participants of the provider-level intervention) and 500 controls over the three-year project period. Secondary data will be abstracted from the Virginia Medicaid and Virginia Care Markers databases to determine study eligibility, to conduct the patient- and provider-level interventions, and to determine study outcomes. During the patient-level intervention, data will be collected on participants' adherence barriers; this information will be used to refer participants to appropriate resources to assist their adherence to ART. During the provider-level intervention data will be collected to inform the peer-to-peer clinician consultation.

CDC requests OMB approval for an estimated 687 burden hours annually. There are no costs to respondents other than their time to participate.

#### Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
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Participants	Verbal consent—participants	460	1	15/60	115
Provider participants	Verbal consent—provider participants	40	1	15/60	10
Participants	Verbal consent—control participants (for participants of provider-level intervention)	40	1	15/60	10
Control participants	Verbal consent—control participants	500	1	15/60	125
PositiveLinks participants	PositiveLinks enrollment	100	1	60/60	100
Participants	Phase I interview	460	1	30/60	230
Participants	Phase II interview	100	1	30/60	50
Advisory Committee to the Virginia Medication Assistance Program member and	Clinician consultation	10	4	30/60	20

other HIV clinical expects					
Provider participants	Clinician consultation	40	1	30/60	20
Advisory Committee to the Virginia Medication Assistance Program member and other HIV clinical expects	Post- consultation questionnaire	10	4	10/60	7
Total					687

**Jeffrey M. Zirger,**

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[FR Doc. 2021-14752 Filed: 7/9/2021 8:45 am; Publication Date: 7/12/2021]